UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

DATE: January 29, 2009

SUBJECT: Preliminary Human Health Assessment for the Registration Review of *Allium satvium* (Garlic).

Registration Review Case #: 4007
PC Code: 128827
CAS #: 8000-78-0
Chemical Class: Biochemical

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THE FOLLOWING CONTAINS CONFIDENTIAL BUSINESS INFORMATION

ACTION REQUESTED

The following is a preliminary human health assessment for the biopesticide *Allium satvium* (Garlic) in support of the development of the Registration Review Work Plan.

RECOMMENDATIONS AND CONCLUSIONS

Executive Summary

Based on the available data and information, the Agency does not foresee the need for new data or for a new human health risk assessment for this active ingredient. Hazard and exposure information as well as Agency risk assessments on *Allium satvium* were evaluated against current safety standards established by the Agency's scientific policies and regulations and it was determined that there is no need to conduct an additional human health risk assessment. *Allium satvium* is a naturally-occurring substance, has a non-toxic mode of action (it is a repellent) and there is a significant history of exposure to humans and the environment. According to the Incident Data System, there have been no reports of incidents from use of products containing garlic oil as an active ingredient. There is reasonable certainty that no harm will result to the general population from exposure to *Allium satvium* in the products containing this active ingredient when they are used according to label instructions.

I. Background

Allium satvium is formulated as a powder or a water-based extract and is listed on labels of registered products as garlic, garlic oil, garlic water and garlic juice. The Agency considers these terms to be synonymous and therefore, they are all listed under the same PC code and CAS Number according to the Agency's databases.

Currently, there are 11 products that are registered containing the biochemical. Two products are insect repellents for agricultural uses and nine products are animal repellents primarily for residential uses. Two of the 11 products contain garlic oil as the only active ingredient. Most of the other products also contain putrescent whole egg solids and capsaicin as active ingredients.

II. Tolerance

Allium satvium is exempt from the requirement of a tolerance as an active or inert ingredient under 40 CFR 180.950(a). The biochemical is exempt from the requirement of a tolerance because is considered a commonly consumed food commodity.

III. Incidents

According to the Incident Data System, there have been no reports of incidents from use of products containing garlic oil as an active ingredient.

IV. Toxicity Profile

Although data on the technical grade of the active ingredient (TGAI) are required under 40 CFR 158.2050, because *Allium satvium* is considered a minimum risk pesticide, is a commonly consumed food commodity and has a significant history of exposure to humans, toxicology data on *Allium satvium* historically have been waived. Based on the available information on this biochemical and its current uses as a pesticide, the Agency will continue to waive generic toxicology data requirements for the TGAI. However, toxicology data requirements must be fulfilled for manufacturing products (MPs) end-use products (EPs) containing this active ingredient. Toxicology data and or rationale to fulfill or waive these requirements are available on the currently registered EPs; all of which indicate that these products are of low toxicity.

When the criteria under 40 CFR 152.25(f) are met, garlic oil is classified as a minimum risk pesticide and products containing this active ingredient are exempt from requirements of FIFRA. Under 21 CFR 182.10 (spices and other natural seasonings and flavorings) and 21 CFR 182.20 (essential oils, oleoresins [solvent-free] and natural extractives [including distillates] as affirmed in 184.1317 [garlic and its derivatives]), garlic is classified as generally recognized as safe (GRAS). *Allium satvium* is broadly available in the United States for human consumption and is valued for its benefits to human health. Based on its composition and physical and chemical properties, garlic is considered to be non-persistent in the environment. It degrades rapidly in the environment and therefore, human exposure to pesticidal residues is expected to be minimal.

Based on the information presented above, the Agency does not foresee the need for new data or for a new human health risk assessment. Additionally, based on the available information, toxicology data requirements for *Allium satvium* are waived. However, registrants will be required to fulfill toxicity data requirements for manufacturing and end-use products containing this active ingredient, unless the criteria under 40 CFR 152.25(f) are met. There is reasonable certainty that no harm will result to the general population from exposure to *Allium satvium* in the products containing this active ingredient when they are used according to label instructions.

V. References

U.S. EPA Reregistration Eligibility Document for *Allium satvium* (128827). Issued June, 1992.

cc: A. L. Gonzales, C. Greene, BPPD Science Review File
A. L. Gonzales, FT, PY-S: 1/29/09